

REMARKS

Applicant submits this Request for Reconsideration in reply to the final Office Action dated August 10, 2004. Claims 1-10, 14-20, and 22-29 are pending in this application, with claims 4-6, 9, 10, 14-20, and 26-29 having been withdrawn from consideration. Claims 1 and 24 are the only independent claims.

As an initial matter, Applicant notes that a copy of the signed Form PTO 1449 that was submitted with the Information Disclosure Statement ("IDS") filed June 16, 2004, was not returned with the Office Action of August 10, 2004. Applicant requests that the Examiner consider the cited references, sign and date the Form PTO 1449 to indicate that consideration, and return the signed form with the next Office Communication. If for some reason, the Examiner is unable to locate the Form PTO 1449 in the PTO file, the Examiner is invited to telephone the undersigned at 202-408-4449 so that a copy of the as-filed IDS materials, including the Form PTO 1449 can be provided.

On pages 2-7 of the final Office Action, claims 1-3, 7, 8, and 22-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,409,019 to Wilk. Applicant respectfully traverses this rejection.

Independent claim 1 recites a method including, among other aspects, "forming a blood flow path from a heart chamber directly to the first coronary vessel via a preexisting natural septal opening extending into the heart wall between the heart chamber and the first coronary vessel." Independent claim 24 recites a method including, among other aspects, guiding a catheter device through an interstitial passageway, "wherein the interstitial passageway includes a preexisting natural septal

opening extending into the heart wall between the heart chamber and the coronary vessel." Thus, each claim recites "a preexisting natural septal opening," i.e., a naturally occurring opening in the heart wall that existed prior to performing the method.

On pages 3 and 6 of the final Office Action, the Examiner admits that "Wilk does not explicitly recite a preexisting natural opening." (See also Office Action at p. 2, stating "Wilk does not explicitly recite to use a preexisting natural opening.") The Examiner then asserts, however, that "it would have been obvious to one with ordinary skill in the art and within the scope of the invention to use a preexisting opening for the purpose of less drilling. The path of least resistance would be to use an area where there would be less channel formation required and this would be obvious to one of ordinary skill in the art at the time the invention was made."

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be satisfied. First, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings." M.P.E.P. § 2142, Original 8th ed., Rev. 2, May 2004, p. 2100-128. Second, "there must be a reasonable expectation of success." *Id.* Third, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." *Id.* Moreover, "[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." (citing *In re Vaeck*, 947 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)). *Id.* In other words, hindsight may not be relied on in establishing a *prima facie* case of obviousness.

The Section 103 rejection based on Wilk fails to satisfy at least the first and third requirements of a *prima facie* case of obviousness. The Examiner's assertion regarding the obviousness to modify Wilk is completely conclusory and unsupported by any evidence, such as teachings found in a secondary reference or otherwise. Quite simply, the Examiner has not provided any evidence whatsoever to support either the alleged teaching of the acknowledged missing disclosure from Wilk or the alleged motivation to modify Wilk in the hypothetical manner suggested in the Office action.

Instead of finding a suggestion or motivation to combine, the first requirement of a *prima facie* case of obviousness, the Examiner appears to be relying on the teachings of the present application as motivation to modify Wilk and, with hindsight, uses Applicants' own disclosure in support of the obviousness rejection. (See Office Action, pages 2 and 3-4.) Such reliance on Applicant's own disclosure and hindsight, however, is improper. Further, to the extent the Examiner is relying on some alleged level of skill in the art as motivation to make the hypothetical modification of Wilk, such a basis for finding motivation also is improper. M.P.E.P. §2143.01 (stating "[t]he level of skill in the art cannot be relied upon to provide the suggestion to combine references.")

Regarding the third requirement of a *prima facie* case of obviousness, the Examiner acknowledges that Wilk, the sole reference relied on in the Section 103 rejection, fails to disclose an aspect of the claimed invention (e.g., the preexisting natural septal opening), as set forth in claims 1 and 24. And the Examiner does not rely on a secondary reference or any other evidence to supply that missing teaching. Thus, contrary to the requirements set forth in M.P.E.P. § 2142, the prior art reference does not teach or suggest all the claim limitations.

To the extent the Examiner may be taking Official Notice to support the acknowledged missing disclosure of or motivation to modify Wilk, the Examiner has not met the requirements for meeting Official Notice as set forth in M.P.E.P. § 2144.03. Moreover, M.P.E.P. § 2144.03 cautions that reliance on Official Notice “should be rare when an application is under final rejection.” Even assuming *arguendo* the Examiner has met such requirements, however, Applicant respectfully traverses such Official Notice because the use of a preexisting natural septal opening in the manner recited in Applicant’s claims is not “of instant and unquestionable demonstration as being well-known.” *Id.* Should the Examiner maintain the claim rejection under 35 U.S.C. §103(a) based on the unsupported allegations about certain subject matter being “obvious to one with ordinary skill in the art and within the scope of the invention,” Applicant respectfully requests that the Examiner either provide documentary evidence or supply a personal affidavit supporting those allegations with the next Office communication so that Applicant will be able to respond in kind. (See M.P.E.P. §2144.03 C.; see also 37 C.F.R. §1.104(d)(2), which requires the Examiner to supply an affidavit in the present circumstances.) For at least these reasons, the Examiner has not met the second criteria in establishing a *prima facie* case of obviousness, and thus Applicant respectfully requests withdrawal of the Section 103(a) rejection.

For at least the reasons above, the Examiner has failed to establish a *prima facie* case of obviousness, and thus Applicant respectfully requests withdrawal of the Section 103(a) rejection based on Wilk.

Because independent claims 1 and 24 are allowable, Applicant respectfully requests rejoinder and allowance of withdrawn dependent claims 4-6, 9, 10, 14-20, and 26-29, as set forth in M.P.E.P. § 821.04.

Claims 2-10, 14-20, 22-23, and 25-29 depend either directly or indirectly from one of independent claims 1 and 24, and are therefore allowable for at least the same reasons that their respective independent claims are allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references and therefore at least some also are separately patentable.

Applicant respectfully requests that in view of this Request for Reconsideration, claims 1-29 are in condition for allowance. There are no proposed amendments to the claims, and thus no new issues are raised and it is not necessary to undertake any additional search of the art by the Examiner. Therefore, this Request for Reconsideration should allow for immediate action by the Examiner.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Request for Reconsideration, it is to be understood that Applicant is in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Request for Reconsideration and charge any additional required fees not otherwise accounted for to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 4, 2004

By: _____



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